

Union Calendar No. 570

110TH CONGRESS
2D SESSION

H. R. 1014

[Report No. 110–874]

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2007

Mrs. CAPPS (for herself and Mrs. CUBIN) introduced the following bill; which was referred to the Committee on Energy and Commerce

SEPTEMBER 23, 2008

Additional sponsors: Mr. GORDON of Tennessee, Mr. ROSS, Mr. OLVER, Mr. McNULTY, Mr. BISHOP of New York, Mr. BUTTERFIELD, Mrs. MCCARTHY of New York, Mr. DELAHUNT, Ms. SLAUGHTER, Ms. LORETTA SANCHEZ of California, Mrs. DAVIS of California, Ms. MCCOLLUM of Minnesota, Mr. TERRY, Ms. HIRONO, Ms. HOOLEY, Ms. KILPATRICK, Mr. MEEHAN, Ms. SCHAKOWSKY, Mr. GRIJALVA, Ms. HERSETH SANDLIN, Mrs. CAPITO, Mr. CLAY, Mr. REYES, Mr. SHAYS, Mr. McDERMOTT, Ms. NORTON, Ms. ESHOO, Mr. CUMMINGS, Mr. BOSWELL, Mr. AL GREEN of Texas, Mrs. TAUSCHER, Mr. PRICE of North Carolina, Mrs. LOWEY, Ms. BORDALLO, Mr. LYNCH, Mr. McCOTTER, Mr. WU, Mr. VAN HOLLEN, Mr. LANTOS, Ms. ZOE LOFGREN of California, Mr. STARK, Mr. HINOJOSA, Mr. HASTINGS of Florida, Mr. GENE GREEN of Texas, Mr. GERLACH, Mr. ELLISON, Mr. BERMAN, Ms. MILLENDER-McDONALD, Ms. LINDA T. SÁNCHEZ of California, Ms. SOLIS, Mr. MELANCON, Mr. PLATTS, Mr. BRADY of Pennsylvania, Mr. RUSH, Ms. BERKLEY, Mr. COHEN, Mr. RODRIGUEZ, Mr. FILNER, Mr. KENNEDY, Ms. SUTTON, Mr. BOUCHER, Mrs. BOYDA of Kansas, Mr. RANGEL, Mr. MARSHALL, Mr. McHUGH, Mr. JINDAL, Ms. FALLIN, Mr. GONZALEZ, Mr. ISSA, Mr. WAXMAN, Mr. HINCHEY, Mr. LAMPSON, Mr. ALLEN, Mrs. NAPOLITANO, Mr. WEXLER, Mr. MARKEY, Mr. SULLIVAN, Ms. MOORE of Wisconsin, Mr. MOORE of Kansas, Mr. ARCURI, Mr. STUPAK, Mr. SAXTON, Mrs. JONES of Ohio, Mr. HONDA, Ms. DELAULO, Mr. ETHERIDGE, Mrs. MALONEY of New York, Ms. JACKSON-LEE of Texas, Mr. ROTHMAN, Mr.

WYNN, Ms. WOOLSEY, Mr. OBERSTAR, Ms. CORRINE BROWN of Florida, Mrs. BONO MACK, Mr. REHBERG, Mr. ORTIZ, Mr. CARSON, Mr. GOODE, Ms. MATSUI, Ms. DEGETTE, Mr. FARR, Mr. ABERCROMBIE, Mr. FERGUSON, Mrs. SCHMIDT, Ms. CASTOR, Ms. GRANGER, Ms. SCHWARTZ, Ms. HARMAN, Mrs. GILLIBRAND, Ms. EDDIE BERNICE JOHNSON of Texas, Ms. KAPTUR, Ms. CLARKE, Mr. LOEBSACK, Mr. PERLMUTTER, Mr. MURTHA, Ms. ROS-LEHTINEN, Mrs. CHRISTENSEN, Mr. THOMPSON of Mississippi, Mr. PASTOR, Ms. BALDWIN, Mr. ALTMIRE, Mr. BONNER, Mr. MCGOVERN, Ms. WATSON, Mr. WAMP, Ms. SHEA-PORTER, Mr. SESSIONS, Mr. BISHOP of Utah, Mr. SOUDER, Ms. LEE, Ms. WASSERMAN SCHULTZ, Mr. ENGEL, Mrs. MYRICK, Mr. TOWNS, Mrs. BLACKBURN, Ms. PRYCE of Ohio, Mr. NEAL of Massachusetts, Mr. MICHAUD, Mr. WELLER of Illinois, Mr. ISRAEL, Mr. KIND, Mr. LANGEVIN, Mr. HARE, Mr. BURGESS, Mr. TIERNEY, Ms. WATERS, Mr. WELCH of Vermont, Mr. PAYNE, Mr. FRANK of Massachusetts, Mr. JOHNSON of Georgia, Mr. WALSH of New York, Mr. KUHL of New York, Mr. KANJORSKI, Mr. LIPINSKI, Mr. MILLER of North Carolina, Mr. FORTENBERRY, Mr. GRAVES, Mr. BURTON of Indiana, Mr. CARTER, Ms. BEAN, Mr. UDALL of Colorado, Mr. JACKSON of Illinois, Mr. BOREN, Ms. ROYBAL-ALLARD, Ms. VELÁZQUEZ, Mr. YARMUTH, Mr. WEINER, Mrs. MILLER of Michigan, Ms. GIFFORDS, Mrs. DRAKE, Mr. DOYLE, Mr. ALEXANDER, Mr. JONES of North Carolina, Mr. PETERSON of Minnesota, Mr. ENGLISH of Pennsylvania, Mrs. BIGGERT, Mr. BARROW, Mr. EMANUEL, Mr. WELDON of Florida, Mr. HOLDEN, Mr. RUPPERSBERGER, Mr. MORAN of Virginia, Mr. GEORGE MILLER of California, Mr. KILDEE, Mr. JEFFERSON, Mr. EDWARDS, Mr. MATHESON, Mr. ROGERS of Alabama, Mrs. EMERSON, Mrs. BACHMANN, Mrs. McMORRIS RODGERS, Mrs. JO ANN DAVIS of Virginia, Mrs. WILSON of New Mexico, Mr. RADANOVICH, Ms. GINNY BROWN-WAITE of Florida, Mr. NADLER, Mr. SIRES, Mr. HODES, Mr. SMITH of New Jersey, Mr. BISHOP of Georgia, Mr. FORTUÑO, Mr. SERRANO, Mr. PICKERING, Mr. ELLSWORTH, Mr. LOBIONDO, Mr. LINCOLN DAVIS of Tennessee, Mr. WOLF, Mr. COURTNEY, Mr. HOLT, Ms. TSONGAS, Mr. CALVERT, Mr. SPACE, Mr. PASCRELL, Mr. CUELLAR, Mr. MCINTYRE, Mr. HALL of Texas, Mr. SMITH of Washington, Mr. CARSON, Mr. LEWIS of Georgia, Mr. RAHALL, Ms. RICHARDSON, Mr. GUTIERREZ, Mr. RAMSTAD, Mr. LINCOLN DIAZ-BALART of Florida, Mr. MARCHANT, Mr. TAYLOR, Mr. KAGEN, Mr. FOSTER, Mr. KIRK, Mr. WALZ of Minnesota, Mr. UPTON, Mr. BLUMENAUER, Mr. TIM MURPHY of Pennsylvania, Mr. WITTMAN of Virginia, Mr. SCALISE, Mr. LAHOOD, and Mr. FATTAH

SEPTEMBER 23, 2008

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on February 13, 2007]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Heart Disease Edu-*
5 *cation, Analysis Research, and Treatment for Women Act”*
6 *or the “HEART for Women Act”.*

7 **SEC. 2. REPORTING OF DATA IN APPLICATIONS FOR DRUGS,**

8 **BIOLOGICS, AND DEVICES.**

9 *(a) DRUGS.—*

10 *(1) NEW DRUG APPLICATIONS.—Section 505(b)*
11 *of the Federal Food, Drug, and Cosmetic Act (21*
12 *U.S.C. 355(b)) is amended—*

13 *(A) in paragraph (1), in the second sen-*
14 *tence—*

15 *(i) by striking “drug, and (G)” and*
16 *inserting “drug; (G)”; and*

1 (ii) by inserting before the period the
2 following: “; and (H) the information re-
3 quired under paragraph (7)”;

4 (B) by adding at the end the following:

5 “(7)(A) With respect to clinical data in an application
6 under this subsection, the Secretary may deny such an ap-
7 plication if the application fails to meet the requirements
8 of sections 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a) of title
9 21, Code of Federal Regulations.

10 “(B) The Secretary shall modify the sections referred
11 to in subparagraph (A) to require that an application
12 under this subsection include any clinical data possessed
13 by the applicant that relates to the safety or effectiveness
14 of the drug involved by gender, age, and racial subgroup.

15 “(C) Promptly after approving an application under
16 this subsection, the Secretary shall, through an Internet site
17 of the Department of Health and Human Services, make
18 available to the public the information submitted to the Sec-
19 retary pursuant to subparagraphs (A) and (B), subject to
20 sections 301(j) and 520(h)(4) of this Act, subsection (b)(4)
21 of section 552 of title 5, United States Code (commonly re-
22 ferred to as the ‘Freedom of Information Act’), and other
23 provisions of law that relate to trade secrets or confidential
24 commercial information.

1 “(D) *The Secretary shall develop guidance for staff of*
 2 *the Food and Drug Administration to ensure that applica-*
 3 *tions under this subsection are adequately reviewed to deter-*
 4 *mine whether the applications include the information re-*
 5 *quired pursuant to subparagraphs (A) and (B).”.*

6 (2) *INVESTIGATIONAL NEW DRUG APPLICA-*
 7 *TIONS.—Section 505(i) of the Federal Food, Drug,*
 8 *and Cosmetic Act (21 U.S.C. 355(i)) is amended—*

9 (A) *in paragraph (2), by striking “Subject*
 10 *to paragraph (3),” and inserting “Subject to*
 11 *paragraphs (3) and (5),” ; and*

12 (B) *by adding at the end the following:*

13 “(5)(A) *The Secretary may place a clinical hold (as*
 14 *described in paragraph (3)) on an investigation if the spon-*
 15 *sor of the investigation fails to meet the requirements of*
 16 *section 312.33(a) of title 21, Code of Federal Regulations.*

17 “(B) *The Secretary shall modify the section referred*
 18 *to in subparagraph (A) to require that reports under such*
 19 *section include any clinical data possessed by the sponsor*
 20 *of the investigation that relates to the safety or effectiveness*
 21 *of the drug involved by gender, age, and racial subgroup.”.*

22 (b) *BIOLOGICS LICENSE APPLICATIONS.—Section 351*
 23 *of the Public Health Service Act (42 U.S.C. 262) is amend-*
 24 *ed by adding at the end the following:*

1 “(k) The provisions of section 505(b)(7) of the Federal
 2 Food, Drug, and Cosmetic Act (relating to clinical data
 3 submission) apply with respect to an application under
 4 subsection (a) of this section to the same extent and in the
 5 same manner as such provisions apply with respect to an
 6 application under section 505(b) of such Act.”.

7 (c) *DEVICES*.—

8 (1) *PREMARKET APPROVAL*.—Section 515 of the
 9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 10 360e) is amended—

11 (A) in subsection (c)(1)—

12 (i) in subparagraph (G)—

13 (I) by moving the margin 2 ems
 14 to the left; and

15 (II) by striking “and” after the
 16 semicolon at the end;

17 (ii) by redesignating subparagraph
 18 (H) as subparagraph (I); and

19 (iii) by inserting after subparagraph
 20 (G) the following subparagraph:

21 “(H) the information required under subsection
 22 (d)(7); and”; and

23 (B) in subsection (d), by adding at the end
 24 the following paragraph:

1 “(7) *To the extent consistent with the regulation of de-*
 2 *vices, the provisions of section 505(b)(7) (relating to clinical*
 3 *data submission) apply with respect to an application for*
 4 *premarket approval of a device under subsection (c) of this*
 5 *section to the same extent and in the same manner as such*
 6 *provisions apply with respect to an application for pre-*
 7 *market approval of a drug under section 505(b).”.*

8 (2) *INVESTIGATIONAL DEVICES.—Section*
 9 *520(g)(2) of the Federal Food, Drug, and Cosmetic*
 10 *Act (21 U.S.C. 360j(g)(2)) is amended by adding at*
 11 *the end the following subparagraph:*

12 “(D) *To the extent consistent with the regulation of*
 13 *devices, the provisions of section 505(i)(5) (relating to indi-*
 14 *vidual study information) apply with respect to an appli-*
 15 *cation for an exemption pursuant to subparagraph (A) of*
 16 *this paragraph to the same extent and in the same manner*
 17 *as such provisions apply with respect to an application for*
 18 *an exemption under section 505(i).”.*

19 (d) *RULES OF CONSTRUCTION.—This Act and the*
 20 *amendments made by this Act may not be construed—*

21 (1) *as establishing new requirements under the*
 22 *Federal Food, Drug, and Cosmetic Act relating to the*
 23 *design of clinical investigations that were not other-*
 24 *wise in effect on the day before the date of the enact-*
 25 *ment of this Act; or*

1 (2) *as having any effect on the authority of the*
 2 *Secretary of Health and Human Services to enforce*
 3 *regulations under the Federal Food, Drug, and Cos-*
 4 *metic Act that are not expressly referenced in this Act*
 5 *or the amendments made by this Act.*

6 (e) *APPLICATION.—This section and the amendments*
 7 *made by this section apply only with respect to applications*
 8 *received under section 505 or 515 of the Federal Food,*
 9 *Drug, and Cosmetic Act (21 U.S.C. 355, 360e) or section*
 10 *351 of the Public Health Service Act (42 U.S.C. 262) on*
 11 *or after the date of the enactment of this Act.*

12 **SEC. 3. REPORTING AND ANALYSIS OF PATIENT SAFETY**
 13 **DATA.**

14 (a) *DATA STANDARDS.—Section 923(b) of the Public*
 15 *Health Service Act (42 U.S.C. 299b–23(b)) is amended by*
 16 *adding at the end the following: “The Secretary shall pro-*
 17 *vide that all nonidentifiable patient safety work product re-*
 18 *ported to and among the network of patient safety databases*
 19 *be stratified by sex.”.*

20 (b) *USE OF INFORMATION.—Section 923(c) of the Pub-*
 21 *lic Health Service Act (42 U.S.C. 299b–23(c)) is amended*
 22 *by adding at the end the following: “Such analyses take*
 23 *into account data that specifically relates to women and*
 24 *any disparities between treatment and the quality of care*
 25 *between males and females.”.*

1 **SEC. 4. QUALITY OF CARE REPORTS BY THE AGENCY FOR**
2 **HEALTHCARE RESEARCH AND QUALITY.**

3 *Section 903 of the Public Health Service Act (42*
4 *U.S.C. 299a–1) is amended—*

5 *(1) in subsection (b)(1)(B), by inserting before*
6 *the semicolon the following: “, including quality of*
7 *and access to care for women with heart disease,*
8 *stroke, and other cardiovascular diseases”; and*

9 *(2) in subsection (c), by adding at the end the*
10 *following:*

11 *“(4) ANNUAL REPORT ON WOMEN AND HEART*
12 *DISEASE.—Not later than September 30, 2009, and*
13 *annually thereafter, the Secretary, acting through the*
14 *Director, shall prepare and submit to Congress a re-*
15 *port concerning the findings related to the quality of*
16 *and access to care for women with heart disease,*
17 *stroke, and other cardiovascular diseases. The report*
18 *shall contain recommendations for eliminating dis-*
19 *parities in, and improving the treatment of, heart*
20 *disease, stroke, and other cardiovascular diseases in*
21 *women.”.*

22 **SEC. 5. EDUCATIONAL CAMPAIGNS.**

23 *(a) DISTRIBUTION OF EDUCATIONAL MATERIAL.—The*
24 *Secretary of Health and Human Services (referred to in*
25 *this section as the “Secretary”) shall develop and distribute*
26 *to females who are age 65 or older, physicians, and other*

1 appropriate healthcare professionals, educational materials
 2 relating to the prevention, diagnosis, and treatment of heart
 3 disease, stroke, and cardiovascular diseases in women. The
 4 Secretary may carry out this subsection through contracts
 5 with public and private nonprofit entities.

6 (b) *HEALTHCARE PROFESSIONAL EDUCATIONAL CAM-*
 7 *PAIGN.*—The Secretary, acting through the Bureau of
 8 Health Professions of the Health Resources and Services Ad-
 9 ministration, shall conduct an education and awareness
 10 campaign for physicians and other healthcare professionals
 11 relating to the prevention, diagnosis, and treatment of heart
 12 disease, stroke, and other cardiovascular diseases in women.
 13 The Bureau of Health Professions may carry out this sub-
 14 section through contracts with public and private nonprofit
 15 entities.

16 **SEC. 6. EXTENSION OF WISEWOMAN PROGRAM.**

17 Section 1509 of the Public Health Service Act (42
 18 U.S.C. 300n–4a) is amended—

19 (1) in subsection (a)—

20 (A) by striking the heading and inserting

21 “IN GENERAL.—”; and

22 (B) in the matter preceding paragraph (1),

23 by striking “may make grants” and all that fol-

24 lows through “purpose” and inserting the fol-

1 *lowing: “may make grants to such States for the*
2 *purpose”; and*
3 *(2) in subsection (d)(1), by striking “there are*
4 *authorized” and all that follows through the period*
5 *and inserting “there are authorized to be appro-*
6 *priated \$37,000,000 for fiscal year 2009, \$38,850,000*
7 *for fiscal year 2010, \$40,792,500 for fiscal year 2011,*
8 *\$42,832,000 for fiscal year 2012, and \$44,974,000 for*
9 *fiscal year 2013.”.*

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